UNITED STATES OF AMERICA
UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

STRYKER CORPORATION, et al.,	)	
	)	
Plaintiffs,	)	Case No. 4:01-cv-157
	)	
v.	)	Honorable Robert Holmes Bell
	)	
NATIONAL UNION FIRE INSURANCE COMPANY OF PITTSBURGH, PA., et al.,	)	**REPORT AND RECOMMENDATION**
	)	
Defendants.	)	
	)	

This is a civil action brought by an insured under a commercial umbrella policy. Plaintiffs seek a declaratory judgment and damages for alleged breach of contract arising from the failure of defendant XLIA to defend and indemnify plaintiffs against more than seventy lawsuits and other claims seeking damages for bodily injury caused by an allegedly defective prosthetic device (the Uni-Knee) sold by plaintiffs. Shortly before jury trial on liability issues was to commence, Chief Judge Robert Holmes Bell issued an order adjourning the trial without date, citing the parties' last-minute raising of new issues for trial. The court directed the parties to meet with me for purposes of delineating the issues to be presented to the jury. (Memorandum Opinion and Order, docket # 756). Pursuant to that direction, I have held two telephone conversations with counsel for plaintiffs and defendant XLIA in an effort to arrive at a form of special verdict delineating the ultimate issues of fact to be determined by the jury at the liability trial.

In the course of reviewing this matter and discussing the issues with counsel, I have concluded that certain dispositive issues determined by the court in the course of its lengthy summary judgment opinions should be revisited. In addition, I am recommending some modification of the tentative special verdict form presented to counsel at the final pretrial conference. After discussing my conclusions at length with counsel, during off-the-record telephone conversations, I am recommending that two issues previously identified as questions of fact for the jury's determination should be decided by the court as a matter of law. If adopted, the recommendations herein promise to simplify an already complicated jury trial.

1. Plaintiffs' Prima Facie Case

In order to prove coverage under the standard language of the XLIA policy, Stryker must show (1) that it is legally obligated to pay "those sums in excess of the Retained Limit," (2) as a result of "bodily injury" that takes place during the policy period, and (3) caused by an "occurrence." (Opinion, docket # 689, at 7-8). The parties have agreed that the first element (whether plaintiffs have paid an amount in excess of the retained limit) should be reserved until the second phase of this litigation, which will be directly concerned with the amounts expended by plaintiffs and the reasonableness thereof. With regard to the second and third elements, the parties disagree sharply concerning plaintiffs' burden. The issues of bodily injury and occurrence are discussed separately below.

A. Bodily Injury

Under the standard language of the insurance policy, coverage is triggered when liability is imposed on the insured "because of Bodily Injury . . . that takes place during the Policy

Period and is caused by an occurrence. . . ." (Policy, ¶ I). Consequently, under the standard language, the trigger of coverage is bodily injury occurring during the policy period, regardless of the date of the occurrence. *See Gelman Sciences, Inc. v. Fidelity & Cas. Co of N.Y.*, 572 N.W.2d 617, 623 (Mich. 1998), *overruled on other grounds by Wilkie v. Auto-Owners Ins. Co.*, 664 N.W.2d 776 (Mich. 2003); *accord, Dow Chem. Co. v. Associated Indem. Corp.*, 724 F. Supp. 474 (E.D. Mich. 1989). With regard to claims involving implantable medical products (such as the Uni-Knee) manuscript endorsement no. 15 provides special rules. This endorsement is titled "Definition of Occurrence – Medical Products." In essence, plaintiffs contend that the intent and effect of endorsement no. 15 was to aggregate all bodily injury claims arising out of one batch of the insured's products, such that all claims arising from the same product defect or deficiency are "telescoped" into one year, regardless of the date when bodily injury was sustained. The court has already determined that endorsement no. 15 is ambiguous in this regard and that parol evidence is admissible to discern the parties' intent. Plaintiffs' contention finds some support in the language of paragraph 2, which provides that "all Bodily Injury . . . which arises out of one batch of the Named Insured's Products shall be considered one occurrence." Although the standard policy language clearly contemplates that the "occurrence" is the cause and "bodily injury" is the effect, the quoted language tends to disclose an intent to equate those two, otherwise distinct, concepts. Plaintiffs also rely on the testimony of Daniel J. Dean, who allegedly was the author of the manuscript endorsement, to support their interpretation. Defendant disputes this interpretation, arguing that the special definition of "occurrence" for implantable medical products in endorsement no. 15 does not relieve the insured of its obligation to show, for each claimant, that bodily injury was incurred during the term of the policy. In my opinion, a reading of the policy as a whole tends to support defendant's

construction, but, as the court has already determined, ambiguities in the endorsement language prevent the court from resolving this issue as a matter of law.

Because the jury must determine the intent of the parties under endorsement no. 15, the jury must answer a special verdict question under alternative assumptions. First, the jury must be asked whether the parties intended under endorsement no. 15 that all personal injury claims arising from one batch of the insured's products should be included in a single policy year, regardless of the date upon which bodily injury occurred. If the jury determines that this was indeed the intent of the parties, then plaintiffs will not be required to show that bodily injury occurred during the term of the policy, but only that an advisory memorandum was issued during the policy period (a fact which has already been agreed to). If, by contrast, the jury answers in the negative, then the provisions of paragraph 1 of the standard commercial umbrella policy continue to apply and would require plaintiffs to show that each claimant incurred bodily injury during the policy period. Hence, the jury must also be given a special verdict question asking whether *each* Uni-Knee claimant incurred bodily injury during the policy period.[1]

B. Occurrence

As noted, the standard language of the commercial umbrella policy requires that bodily injury be caused by an "occurrence." The standard policy definitions (¶ IV H) define "occurrence" to mean an accident, including continuous or repeated exposure to conditions, which results in bodily injury neither expected nor intended from the standpoint of the insured. With regard to implantable medical products only, however, endorsement no. 15 contains numerous provisions

[1]The recommendations made in this section do not require revisiting any summary judgment decisions previously made by the court, but only involve a modification of the verdict form.

that affect the definition of occurrence. Relying on the first sentence of paragraph 1 of the endorsement, defendant has argued that "occurrence" means only the explant of a medical product. In its opinion of August 17, 2005, the court determined that paragraph 1 is ambiguous and that it is unclear whether an explant is necessary for the existence of an occurrence under the policy. Consequently, the court determined that neither party was entitled to summary judgment and that the question whether an explant was necessary for the existence of an occurrence was a question of fact for the jury. (Opinion, docket # 689, at 7-12).

Although the existence of an occurrence in the absence of an explant is indeed ambiguous under paragraph 1 of endorsement no. 15, the issue is mooted by the provisions of paragraphs 2 and 3, which introduce the concept of batch coverage. Paragraph 2 provides that for the purpose of determining the company's limits of insurance and the insured's self-insured retention amounts, all bodily injury which arises out of one batch of the named insured products shall be considered "one occurrence." Paragraph 3 goes on to define a "batch" as all medical products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum. Paragraph 3 (as clarified by endorsement no. 17) then provides that the date of the advisory memorandum "will be considered the date of occurrence for all claims resulting from or relating to the batch." Read as a whole, endorsement no. 15 (as clarified by endorsement no. 17) is not ambiguous with regard to the "batch" situation now facing the court, although the endorsement is ambiguous with regard to isolated product liability claims dealt with in paragraph 1.

The defendant insurance company has repeatedly admitted that the claims and lawsuits involving the Uni-Knee products at issue in this case constitute a single batch.[2] By admitting that all Uni-Knee claims fall into one batch, defendant also admits, *ipso facto*, that there was an occurrence. Under paragraph 3, "the date of the advisory memorandum will be considered the date of occurrence for all claims resulting from or relating to the batch." Consequently, it is beyond genuine issue that an occurrence existed and that the date of the occurrence was July 28, 2000 (the date of the advisory memorandum). Defendant cannot admit that a batch exists and at the same time contest the existence of an occurrence.

Defendant relies on the first sentence of paragraph 1 to mechanistically substitute the word "explant" for "occurrence" in the basic words of coverage, so that, for each claimant, the insured would be required to show "Bodily Injury that takes place during the Policy Period and is caused by an ⟨explant⟩." This approach ignores the rest of endorsement no. 15, especially the batch coverage provision, which all parties agree apply to this case. For claims in a batch, there is but a single occurrence, involving "all medical products which have the same known or suspected defect." (End. no 15, ¶ 3, emphasis added). Consequently, the appropriate substitution of the words of coverage in the batch situation involved in this case is "Bodily Injury . . . that takes place during the Policy Period and is caused by ⟨the defect identified in the advisory memorandum⟩."

If adopted, defendant's construction would require an insured to prove a separate "occurrence" falling within the Policy Period for each claimant, in addition to proving a batch

---

[2] *See, e.g.*, Defendants' Denial of Coverage Letter dated October 11, 2001, at p. 5 ("Consequently, we agree that the Uni-Knee products at issue in the claims and lawsuits will constitute one 'batch.'").

occurrence. This result is illogical and finds no support in the policy language. The entire purpose of paragraphs 2 and 3 of endorsement no. 15 is to relate all claims involving the same defect to a single occurrence. Contrary to the clear intent, defendant would require the establishment of seriatim occurrences for every claim within the batch. Nothing in the policy requires an insured to establish the existence of an occurrence during the policy period or to establish more than one occurrence supporting one batch of claims.

I therefore recommend that the court grant plaintiffs a summary judgment on the issue whether an occurrence existed regarding the Uni-Knee batch. Regarding plaintiffs' prima facie case, this leaves for the jury's resolution only the issues identified in section I.A. above – whether all claimants in the batch must have incurred bodily injury during the policy period and whether each claimant did so.

2. Affirmative Defense

Relying on the last sentence of paragraph 3 of endorsement no. 15, defendant has asserted an exclusion from coverage. That sentence provides as follows: "Batch coverage shall not apply to any loss, which arises out of a defect, or deficiency that is known or suspected prior to 1-1-00." The court's previous opinions have identified three factual questions relevant to the existence of this exclusion:

> (1) What is the defect about which plaintiffs were required to have knowledge or suspicion before the relevant date?
>
> (2) Is knowledge or suspicion by any employee sufficient, or did the parties intend that only knowledge by officers or risk managers would exclude coverage?

> (3) Did the requisite officers or employees of plaintiffs know of or suspect the defect before the inception date of the policy?

The first issue – the definition of the defect identified in the advisory memorandum – was treated by the court in its opinion of December 1, 2004. (docket # 619). The parties had presented the court with widely divergent definitions of the defect at issue. Defendant contended that the Uni-Knees were defective because they were irradiated with gamma rays in air and therefore would oxidate over time. Plaintiffs defined the defect in the Uni-Knee as, "they were packaged in air and sterilized by gamma irradiation and then implanted after being stored on the shelf for an extended period of time (5 years) prior to implantation." (See Opinion, docket # 619 at 6). Essentially, Stryker argued that the defect in the Uni-Knee was its *implantation* after the intended shelf life. (*Id.*) The court determined that the definition of the defect described in the advisory memorandum framed a question of fact for resolution by the jury.

During off-the-record telephone discussions, both counsel agreed that this issue was not a question of fact, that it was inappropriate for a jury's determination, and that the parties in any event would be unable to offer substantial proofs to help the jury resolve this question. I concur. This issue must be resolved by the court as a matter of law.

Under the clear language of endorsement no. 15, paragraph 3, a known or suspected defect or deficiency is identified by an advisory memorandum. The parties concur that the relevant advisory memorandum was dated July 28, 2000. The relevant language in the advisory memorandum is as follows:

> It has come to Howmedica Osteonics' attention that between January 1997 and April 2000 a number of Duracon Unicompartmental Knee tibial components were implanted four or more years after they were sterilized and placed into inventory. At the time which these

> components were manufactured, Howmedica, Inc. packaged the products in standard atmospheric conditions and utilized the process of gamma radiation to sterilize the products. Some published studies indicate that the polyethylene components processed under these condition may be susceptible to oxidation and the potential for increased wear if they resided on the shelf for an extended period of time prior to implantation. It is believed that issues unique to unicompartmental knees may make them more susceptible to early wear under these conditions.

(Op., docket # 619 at 4).

Liability insurance policies are written against the backdrop of general tort law, which defines the liabilities to which the insured is exposed and against which the insurance company is agreeing to defend and indemnify the insured. Under Michigan product liability law, a product is defective if it is not reasonably safe for its foreseeable uses. *See Ghrist v. Chrysler Corp.*, 547 N.W.2d 272, 275 (Mich. 1996). The general tort law of the states is in agreement. *See, eg. Kallio v. Ford Motor Co.*, 407 N.W.2d 92, 94 (Minn. 1987) (to establish that a product is defective, plaintiff must show that it is unreasonably dangerous); *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983) (product is defective when it presents an unreasonable risk of harm to the user); *see generally* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 (1998). In light of this definition of a product defect, which is nearly universal in this country, plaintiffs' proffered construction of the advisory memorandum is untenable. The evidence in this case is undisputed that the UHMWPE plastic used in the Uni-Knee, when sterilized by gamma radiation in the air, begins to deteriorate and becomes unsuitable for use after approximately five years. Consequently, the Uni-Knees had a limited shelf life. They were not "defective," within the meaning of products liability law, at the time of their manufacture or for the next five years. They became defective – not reasonably safe for their foreseeable use – after expiration of their shelf life. Contrary to plaintiffs' suggestion, the

Uni-Knee products did not first become defective only upon implantation. They were defective after the expiration of their shelf life. This is also the only plausible definition of the defect identified in the July 28 advisory memorandum. Under paragraph 4 of endorsement no. 15, an advisory memorandum is a communication from the insured made for the purpose of informing the public "of a risk of substantial harm from the medical product in commercial use." The risk of substantial harm identified in the July 28 advisory memorandum was not limited to those Uni-Knees already implanted, but extended to any Uni-Knee held in inventory after expiration of its shelf life.

Under the definition of "defect" adopted herein, the defendant will have the burden of proving that Stryker knew or suspected, before the policy inception date, that Uni-Knees were available in inventory for implantation by physicians after the expiration of their shelf life. Such products, available for their intended use (implantation) posed an unreasonable risk of harm to the patient and were therefore defective.

Plaintiffs nevertheless argue that in the context of an insurance policy, there could be no defect before implantation because the product had not yet been used and therefore no claim could have arisen. In making this argument, plaintiffs fail to focus on the context in which the words "defect or deficiency" appear. The entire purpose of endorsement no. 15 was to modify the meaning of the word "occurrence" in the insurance policy. One of the provisions of endorsement no. 15 was to create a "batch" for medical products which had the same known or suspected defect or deficiency. In order for a batch to exist, it is not necessary for a claim to have arisen. The last sentence of paragraph 3 does not require that the "loss" arise before the policy inception date, but only that the insured know of or suspect a "defect" before the inception date. Presumably, it is possible for an insured to know of the existence of a defective product years before any injury or

claim arises as a result of that defect. In short, plaintiffs' argument that no defect exists until the deteriorated Uni-Knee is actually implanted in a patient has no support in the words of the policy or general product liability law.

For the foregoing reasons, I recommend that the court determine as a matter of law that the defect identified in the advisory memorandum was the deteriorated condition of Uni-Knees caused by their retention in inventory for use beyond their shelf life.

Recommended Disposition

For the foregoing reasons, I recommend as follows:

A. That the special verdict form propose alternative questions on the issue of bodily injury;

B. That the court grant plaintiffs' summary judgment to plaintiffs on the issue of the existence of an occurrence; and

C. That the court determine, with regard to the exclusion in paragraph 3 of endorsement no. 15, that the relevant issue is whether plaintiffs knew or suspected, before the policy inception date, that Uni-Knees were held in inventory beyond their shelf life.

Dated: September 26, 2005

/s/ Joseph G. Scoville
United States Magistrate Judge

NOTICE TO PARTIES

Any objections to this Report and Recommendation must be filed and served within ten days of service of this notice on you. 28 U.S.C. § 636(b)(1)(C); FED. R. CIV. P. 72(b). All objections and responses to objections are governed by W.D. MICH. LCIVR 72.3(b). Failure to file timely objections may constitute a waiver of any further right of appeal. *See Thomas v. Arn*, 474 U.S. 140 (1985); *Neuman v. Rivers*, 125 F.3d 315, 322-23 (6th Cir.), *cert. denied*, 522 U.S. 1030 (1997); *United States v. Walters*, 638 F.2d 947 (6th Cir. 1981).